

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 April 2001 (26.04.2001)

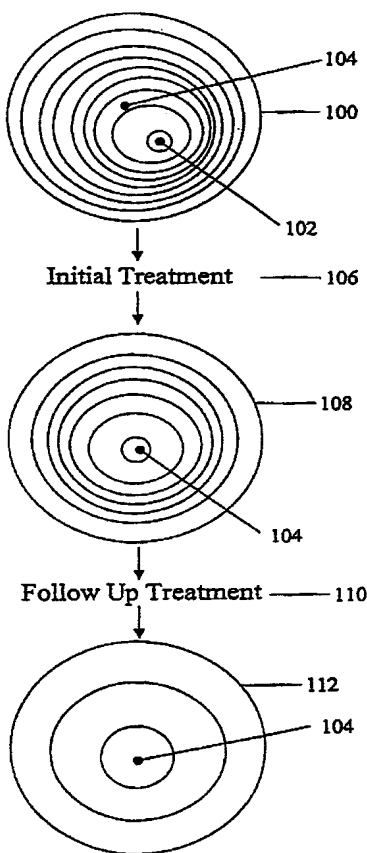
PCT

(10) International Publication Number
WO 01/28477 A1

- (51) International Patent Classification⁷: **A61F 9/01**
- (21) International Application Number: **PCT/EP00/10377**
- (22) International Filing Date: **20 October 2000 (20.10.2000)**
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
199 50 789.9 21 October 1999 (21.10.1999) DE
100 14 481.0 23 March 2000 (23.03.2000) DE
- (71) Applicant (for all designated States except US): **TECHNOLAS GMBH OPHTHALMOLOGISCHE SYSTEME [DE/DE];** Max-Planck-Strasse 6, 85609 Dornach (DE).
- (72) Inventors; and
(75) Inventors/Applicants (for US only): **HOHLA, Kristian [DE/DE];** Johann-Strauss-Strasse 15, 85591 Vaterstetten (DE). **YOUSSEFI, Gerhard [DE/DE];** Reichardtstrasse 1, 84028 Landshut (DE).
- (74) Agent: **VOSSIUS & PARTNER;** Siebertstrasse 4, 81675 München (DE).
- (81) Designated States (national): **AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.**
- (84) Designated States (regional): **ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian**

[Continued on next page]

(54) Title: **MULTI-STEP LASER CORRECTION OF OPHTHALMIC REFRACTIVE ERRORS**



(57) Abstract: A technique of refractive eye correction employs multiple steps to correct refractive errors in the eye. In the first step, gross decentrations of the refractive error are corrected, allowing the subsequent steps to be relatively symmetric in their treatment profile. Then, the eye's refractive error is again measured, and a subsequent treatment is applied for the remaining error. The overall treatment is thus completed in two or more steps.

WO 01/28477 A1



patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

MULTI-STEP LASER CORRECTION OF OPHTHALMIC REFRACTIVE ERRORS

SPECIFICATION

TECHNICAL FIELD

The invention generally relates to refractive correction systems, and more particularly, to a technique for correcting refractive errors in multiple steps.

BACKGROUND ART

The field of ophthalmology for the past number of years has seen great strides in the development of refractive treatments intended to correct the vision of the eye. These techniques have evolved from the earlier radial keratotomy technique, in which slits in the cornea allowed the cornea to relax and reshape, to present techniques including photorefractive keratectomy ("PRK"), anterior lamellar keratectomy ("ALK"), laser in situ keratomileusis ("LASIK"), and thermal techniques such as laser thermal keratoplasty ("LTK"). All of these techniques strive to provide a relatively quick but lasting correction of vision.

At the same time, the diagnostic tools to determine what correction is needed have also advanced. A variety of new topography systems, pachemetry systems, wavefront sensors, and overall refractive error detection systems can detect not only the amounts of myopia, hyperopia, and astigmatism, but also, higher order aberrations of the eye, shapes and thickness of eye components and a host of diagnostic information for therapeutic use such as correcting or modifying the refractive properties of the eye; i.e., creating better vision. These diagnostic systems and techniques have the potential for permitting correction of both the fundamental and higher order defects, especially when used with even more refined refractive correction techniques, with the possibility that vision correction to better than 20/20 will someday be the norm.

A number of these higher order defects can be either induced by unsuccessful refractive treatment or can be inherent problems with the eye. For example, both radial keratotomy and laser refractive techniques can result in an asymmetric vision correction profile for a variety of reasons. Radial keratotomy can result in an over- or under-relaxation of one portion of the eye relative to the other, whereas laser techniques, especially if not properly centered, can result in a vision correction profile that is off of the optical or visual axis or some other axis of treatment. Advanced laser refractive techniques have in fact been used to subsequently correct for these off axis or otherwise asymmetric refractive errors. Moreover, photorefractive laser surgery for correction of myopia, hyperopia and/or astigmatism has been shown to induce higher order defects, both symmetrical such as spherical aberration and asymmetrical such as coma.

SUMMARY OF THE INVENTION

According to one feature of the invention, a technique is provided for correcting for asymmetric errors, i.e., defects that vary in magnitude about a defined reference axis, of the eyes in more than one step. First, one or more of a variety of diagnostic tools, such as, preferably a surface elevation-based topography system, or, alternatively a wavefront sensor, is employed to determine the refractive correction necessary to correct an off-axis (decentered) or otherwise asymmetric refractive error. Then, a treatment profile is calculated which does not necessarily fully correct vision, but rather converts, via partial correction; the off axis and/or asymmetric error into a relatively symmetric error. Then, the refractive error of the eye is again examined, and a follow-up treatment is performed to take the then partially corrected vision to fully corrected vision by correcting the residual symmetric defect.

Sometimes, when an asymmetric error is treated, the actual refractive results that do not necessarily match the predicted results. This can be for a variety of reasons. For example, an irregular thinning of the cornea can cause a reshaping of the cornea, which may be difficult to factor into calculations. This may depend upon the healing response, epithelial regrowth, etc. Further, ablation patterns are typically designed based upon a predicted amount of tissue removal per shot, but the actual ablation value can vary. Also, the refractive treatment can affect the tension in collagen fibers in the cornea

causing reshaping. By first "pretreating" the eye to convert an asymmetric and/or off-axis error into a relatively on-axis and/or otherwise symmetric error, a more symmetric, and empirically verified treatment profile can then be applied to the eye. The follow-up treatment can occur within a very short period of time after the initial treatment, or can occur a matter of days or weeks later, as limited by physiological or other factors.

It will further be appreciated that the multistep treatment described herein is not limited merely to an asymmetric, then symmetric correction. Obviously, an initial step of "regularizing" a cornea must be followed up on the basis of any biodynamic response observed, which could require an asymmetric treatment also for the secondary treatment. Moreover, the multistep treatment comprises, in an embodiment of the invention, correcting lower order aberrations (Zernike 2nd order) with the primary treatment and higher order aberrations (3rd and higher Zernike order) with the secondary treatment. The general concept of the invention, therefore, is to provide a converging solution to the problem of refractive error correction such that subsequent responses to a treatment decrease which then requires a decreased subsequent treatment and so on.

The treatment steps are referred to as an initial, "centering" treatment and then a follow-up treatment preferably on a computer that calculates courses of treatment for a laser system.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of refractive profiles illustrating steps of a technique according to the invention;

Figures 2A-2C are a cut-away profiles of a cornea illustrating steps of a technique according to the invention;

Figure 3 is a flow diagram showing steps of a method according to the invention;

Figures 4A and 4B are profiles of refractive treatment profiles corrected according to the invention; and

Figure 5 is a diagram illustrating a typical diagnostic and treatment system according to the invention.

MODE(S) FOR CARRYING OUT THE INVENTION

Turning to Figure 1, illustrated are the steps of one technique implemented according to the invention. Generally, one of a variety of techniques, preferably topographically based, but including others as described below, determines the refractive error profile of the eye. Based on that error, a corresponding partial refractive treatment is then calculated that is sufficient to generally "re-center" and/or symmetrize the remaining refractive error. The treatment is applied, and the remaining refractive error profile of the eye is again measured. Based on this remaining error, a second treatment is calculated and applied to the eye. The initial treatment thus performs the bulk of the decentered off axis, or asymmetric correction, and the subsequent treatment is substantially symmetric.

Referring to Figure 1, shown is a representation of a refractive profile 100 of a typical eye which can be treated according to this technique. As shown, it includes a refractive error that has a center 102, which is away from a center 104 of the eye. As used herein, the term "center of the eye" refers to a visual axis of the eye defined typically by fixation and alignment, and corresponding with a measurement axis of the diagnostic or therapeutic device, as is well understood by those skilled in the art. The refractive profile 100 corresponds to a variety of different representations of refractive error in the eye. The profile 100 can correspond to a topography map of a surface topography of the eye provided by a typical topography system. One such system was the ORBSHOT™ by Orbtex, Inc., of Salt Lake City, Utah, which produced a variety of representations of the eye's refractive error, including topography maps and dioptric error maps based on the surface topography of the eye. The profile 100 can also represent the error of the overall optical path of the eye, rather than only the surface. Some systems use algorithmic techniques to derive such errors based on the profiles of various optical surfaces in the eye. One such system is the ORBSCAN II® by Bausch & Lomb/Orbtex, which uses surface elevations and ray tracing to determine refractive errors in the eye. Other systems use direct measurements of such errors, such as the wavefront sensor described in U.S. Patent No. 5,777,719 to Williams et al. Further, combinations of techniques can be used to determine the refractive error profile 100 and a variety of other techniques can be used.

Once this error profile 100 is developed, an initial treatment is developed in a step 106. Creating appropriate treatment profiles from error profiles is well known to the art. Generally, the initial treatment 106 is of a profile that will result in the eye's remaining refractive error being substantially symmetric and on-axis. It need not be perfectly so, because the purpose of the initial treatment is to ensure the subsequent treatment, discussed below, does not have gross volumetric asymmetries. But generally, the initial treatment 106 will be sufficient to remove gross asymmetries. Examples of the initial treatment 106 are discussed below in conjunction with Figures 3A-3B. This initial treatment 106 can be developed in a number of ways. Assuming excimer laser surgery is to be performed, for example, a volumetric removal treatment profile for fully correcting the refractive errors of the eye can be developed based on the error profile 100. Then, software can determine a minimum asymmetric treatment profile necessary to yield a remaining treatment profile that is substantially symmetric on the eye. Alternatively, the initial treatment 106 may be more extensive, including a portion of the treatment necessary for the symmetric error correction as well.

In any case, once this initial treatment 106 is derived the eye is treated, whether by LASIK, PRK, thermal techniques, or any of a variety of other techniques that have been or will be developed. This results in the eye having a new, intermediate refractive error profile 108, which is generally substantially symmetric about the approximate center 104 of the eye. The initial treatment 106 will necessarily have resulted in removal of more tissue on one portion of the eye than the other, as is illustrated in Figures 2A-2C below. The intermediate profile 108 is generally symmetric about the axis 104, but may be radially symmetric or axially symmetric. Alternatively, the initial treatment 106 could include correction for astigmatism, yielding a generally radially symmetric profile as the profile 108.

Further, the profile 108 is generally symmetric, but may include higher order, but minor, errors to be corrected, for example, through laser profiling. Again, the point of the initial treatment 106 is to remove the majority of the tissue necessary to generally center and symmetrize the intermediate refractive profile 108. This reduces the effects of gross asymmetries in subsequent treatment; thus, the results of the subsequent treatment become more predictable.

After the initial treatment 106, with LASIK, preferably the flap would be replaced on the eye, which then is allowed to heal – a relatively short process. Alternatively, the eye can be immediately analyzed to determine the results of the LASIK treatment, perhaps adjusting the analysis based on known effects of edema, or swelling. Then, the eye is again refractively analyzed, again using one of a variety of techniques. At this stage of analysis, the same or a different refractive diagnostic tool can be used as is used in diagnosing the initial profile 100, and the tool can even be built into the laser treatment station.

A follow-up treatment 110 appropriate to correct the intermediate refractive error profile 108 is derived, and that treatment is then applied, yielding a final profile 112, preferably the perfect profile for perfect refractive correction of the eye, yielding emmetropia. This is centered at the eye's center 104, and although a slight topography is shown, preferably this topography is the topography necessary to yield perfect vision correction.

Turning to Figures 2A-2C, illustrated is a side profile view of a cornea 200 illustrating the steps implementing a technique according to the invention. In Figure 2A, assume the cornea 200 has previously been treated to correct for myopia using a treatment profile 202, but this treatment profile was unfortunately misaligned on an axis 204. This has yielded a cornea surface defined by the line 206, resulting in an off-center refractive profile, such as the profile 100 of Figure 1. It is this refractive profile 100 which is to be corrected. Turning to Figure 2B, a tissue removal is calculated to yield a treatment profile that removes a section of tissue 208, which corresponds to the treatment necessary to convert the off-axis refractive profile 100 of Figure 1 to the on-axis refractive profile 108. Then turning to Figure 2C, a subsequent portion 210 is removed in the follow-up treatment 110 of Figure 1, correcting for a remaining amount of myopia.

As discussed in conjunction with Figure 1, the refractive profile can be defined in a number of ways. For example, the tissue 208 to be removed to Figure 2B could be that tissue necessary to theoretically yield a symmetric refractive profile defined in terms of cornea elevation. The previously discussed ORBSCAN II® topography system by Bausch & Lomb/Orbtek defines various refractive surfaces in terms of elevation, and can define both surface elevations of the anterior surface of the eye and elevations of the

posterior surface of the cornea as well. Other systems define the refractive profile in terms of directly measured corneal curvature instead of surface elevation. Although such systems ultimately measure the same types of topographies, they do so employing different techniques, and each type of system has advantages.

Rather than defining the desired intermediate refractive profile 108 in terms of surface topography, the goal can be to achieve a cornea with a symmetric corneal thickness. For example, it may be desired to make the initial treatment 106 such that the cornea thickness is essentially the same at a predetermined distance from the center of the cornea. This forms a regular cornea thickness rather than a regular anterior surface profile (although the two will typically be similar). But starting from this regular cornea thickness, the eye can then be treated to refractively correct the remainder of the errors and the follow-up treatment 110.

Illustrating the typical steps that would be applied, Figure 3 illustrates first at step 300 a diagnostic refractive analysis is performed on the eye, then at step 302 the appropriate treatment is applied to correct for the determined decentration and/or asymmetry. The results are then analyzed in a step 304, which can occur minutes, hours, days, or weeks later, and then the further refractive corrections are applied at steps 306.

When an eye requires an irregular treatment profile, the desired result is a symmetric refractive profile, but the very fact that the treatment profile applied is irregular can induce irregularities in the resulting refractive profile of the eye. For example, the thinning of one portion of eye relative to the other can induce its own refractive effects. Thus, the follow-up treatment 110 will generally correct not only myopia or hyperopia, and certain higher order effects, but will also correct for any unpredicted refractive error induced by the initial treatment 106. In any case, the follow-up treatment 110 will typically be far less asymmetric than the initial treatment 106, thus only minimally inducing additional asymmetric refractive error. It is further possible to perform the process in more than two steps, having a further follow-up treatment for slight decentration that may result. This may be indicated for particularly gross asymmetries.

There are other reasons for attempting to create a regular refractive error profile in the initial treatment 106 to be corrected in the follow-up treatment 110. While an

excimer laser, for example, can very precisely remove tissue from the cornea, the actual treatment profile necessary to correct for different degrees of myopia, hyperopia, and astigmatism have been found to require adjustment based on empirical results. These adjustments can depend on many factors, such as the amount of correction, and whether a treatment is an initial treatment or a subsequently performed treatment.

Thus the general embodiment of the invention is to obtain a diagnostic measurement of the patient's eye and to make a first-stage treatment preferably to remove or correct gross defects. The eye's response to the surgical trauma, which may comprise merely the flap cut of a LASIK procedure, is observed. Based upon the observation of the biodynamic response, a second-stage of the multi-stage treatment is performed. Again, the biodynamic response is observed and treatment is continued as appropriate or is considered complete. The preferable outcome is a converging solution embodied by a progressively smaller response and/or more complete correction after each treatment stage.

The empirical results of a number of standard types of treatments generally become established over a large number of treatments. For example, in certain circumstances and conditions one may find an ablation rate in corneal tissue of .35 microns removed by a 120 mjoule per square centimeter per shot (a variety of rates are possible, however). If one were to assume such an ablation rate, one would typically find that ablation on a PMMA plate with the theoretically calculated profile would yield the theoretically predicted amount of correction for both myopia and hyperopia. In practice on an actual cornea, however, a single, fixed ablation rate may not yield the result predicted based on a uniform ablation rate; instead, the amount of ablation necessary is typically dependent on whether myopia or hyperopia is to be treated, and the amount of treatment. For example, to treat for -6.00 diopters of myopia, instead of assuming the ablation rate of 0.35, one might use a theoretical ablation rate of 0.46 to calculate the treatment profile. Thus, the treatment profile desired would be a standard treatment profile for -6.00 diopters of myopia, but multiplied by $0.35/0.46$. Therefore, the actual treatment profile employed would be the equivalent of theoretical treatment for approximately -4.50 diopters of myopia. Put another way, less ablation is needed than is theoretically predicted. On the other hand, to treat for hyperopia, such as +6.00 diopters

of hyperopia, an ablation rate of 0.25 microns per shot can be used in the calculation, and thus to treat for hyperopia of +6.00 diopters, one would actually apply an ablation profile that would theoretical yield the result of +8.40 diopters assuming a constant ablation rate. Alternatively, one could assume a fixed ablation rate but instead scale the desired treatment. That is, one could scale down the treatment to be calculated for myopia from -6.000 to -4.50, and scale up the treatment to be calculated for hyperopia from +6.00 to +8.40. Similarly, the amount of under/overtreatment necessary could be quantified as a percentage. For example, it could be empirically determined that for myopia within a particular range, the actual treatment should only be 75% of the otherwise calculated treatment; for hyperopia, perhaps, a 135% scaling factor is appropriate. The point of all this is not the specific empirical treatments that are developed and how they differ from simplified theoretical calculations based on constant ablation rates, but rather the fact that such empirically developed treatments often yield better results than treatments based purely on theory. By placing the eye in a condition for which many previous treatments have been performed – such as myopia or hyperopia with varying amounts of astigmatism – that empirical data and experience can be brought into play.

There are a variety of reasons that the empirical data diverges from the theoretically predicted outcomes. The cornea tissue is made up of collagen fibers, which are under tension. When the ablation “cuts” those fibers, it could allow additional water to be absorbed into the collagen, effecting the resulting ablation profile. The result could also be influenced by the thinning of the cornea, and the resulting “bulging” of the treated cornea. Also, the deviation of actual treatments from theoretical results is important in subsequent ablation treatments. It has been seen that when performing a follow-up ablation on a cornea, far less actual ablation is necessary than would be predicted to achieve a desired result. Therefore, only a portion of the predicted ablation is needed. Typically, this would range somewhere between 40 to 80% of the theoretically predicted amount of ablation needed, and preferably around 60% of the theoretically required ablation.

As additional empirical data is gathered, it can yield ever more precise results and take into account additional variables. For example, the thickness of the cornea, whether the treatment is a “retreatment”, and other variables could eventually be factored into the

empirically developed treatment. Further, empirical data may further provide courses of treatment not only for myopia, hyperopia, and astigmatism, but also for higher order errors. But again, by achieving a known “starting point”, that data can be brought to bear.

The overall effect of these differences between the theoretical outcomes and the empirical outcomes is that it is preferable in a two step treatment to employ the initial treatment 106 to yield a resulting refractive error profile 108 for which empirical data is available. Thus, if the initial treatment 106 yields a refractive error profile 108 that, for example, simply requires -2.00 diopters of myopic correction with -1.00 diopter of astigmatism, generally such refractive treatments will have historical, empirical data from which surgeons can draw, thus appropriately adjusting any theoretical ablation profile to yield the actual desired result.

Figures 4A and 4B show two alternatives of how to calculate both the initial treatment 106 and the follow-up treatment 110. In Figure 4A, the preferred approach shown is a cutaway side view of an overall treatment profile 400 derived from the refractive error profile 100 of Figure 1. This overall treatment profile 400 is exemplary of a course of volumetric removal using a LASIK technique, for example, that would correct for the refractive error profile 100 of an eye. Typically, such treatments have historically been applied in a single step. As discussed above, according to the techniques of the invention, however, the treatment is applied in two steps, the first being a course of treatment 402 illustrated by the crosshatched area, and the second being a generally symmetric course of treatment 404. To develop this two-step approach, first the necessary refractive profile 400 is developed based on the refractive error profile 100. Then, in Figure 4A, software determines a largest symmetric profile of tissue removal 406 that could be removed given the overall profile 400. Then, that treatment 406 is “subtracted out” of the treatment profile 400, yielding the appropriate treatment profile 402 to correct for the gross decentration and other asymmetries. Then, the profile 402 is removed in the initial treatment 106, the eye is again refractively analyzed, and then a follow-up treatment provided for what remains. As discussed above, it will be appreciated that this follow-up treatment generally be of a similar profile as the profile

404, but not necessarily identical, as the eye may have slightly changed shape as a result of the initial treatment 106 in which the profile 402 was removed.

Figure 4B illustrates yet another, alternative approach starting from the same profile 400, but in this case removing a larger amount of tissue in an initial profile 408. In this case, a symmetric treatment profile 410 is calculated, but not to be the maximum symmetric treatment that could be applied to the eye. Instead, lesser symmetric treatment profile 410 is subtracted from the overall treatment profile 400. Then, the initial treatment 106 is provided using the profile 408.

In this approach of Figure 4B, the initial treatment 106 can yield a result that is “closer” to the final desired result, but still leaving enough of a “cushion” that more or less tissue can be removed than would otherwise be predicted by the treatment profile 410. That is, if the entire treatment 400 was initially performed on the eye, and then a follow-up treatment 110 was applied, extra tissue would typically be removed that would otherwise not have to be removed employing the two-step approach. Leaving the symmetric under-correction represented by the intermediate refractive profile 108, the follow up treatment 110 removes a precise necessary amount of tissue yielding a predictable result. A problem with this approach, however, is that the greater the amount of tissue removed in the initial treatment 106, the greater the unpredictability of such treatment, making it more difficult to yield a symmetric refractive error profile as the refractive error profile 108 for the follow-up treatment 110.

In sum, while even symmetric treatments for conditions such as myopia, hyperopia, and astigmatism typically yield refractive end results that differ from the predicted result, these differences are predictable based on empirical data. That is, based on corneal thickness, surface profiles, previous treatments, and other parameters, doctors can predict how much to “adjust” the actual course of refractive treatments to yield the optimal end result. So employing techniques according to the invention, as illustrated in Figures 4A and 4B, the eye is first treated such that it still has a refractive error remaining, but this refractive error is such that it can be very predictably treated. The first step thus eliminates gross asymmetries in the eye, yielding a generally symmetric profile (although still with some higher order irregularities and some low order

irregularities) and then the residual, preferably symmetric refractive error profile can be very predictably treated yielding the desired end result.

Turning to Figure 5, shown as a typical combination of a topography system T, a computer system C, and an excimer laser eye surgery system E, coupled to perform techniques according to the invention. Such a system is described, for example, in U.S. Patent No. 5,891,132 to Hohla, which is hereby incorporated by reference. Topography system T can be one of the above-described systems, or other refractive diagnostic system and the computer system C is generally a personal computer compatible with the IBM PC by International Business Machines, preferably including a fairly high-powered processor. The laser system E can be a variety of systems, including the Keracor 217 by Technolas GmbH of Dornach, Germany.

Generally, the computer system C runs the software which develops a course of treatment based on parameters provided by the physician as well as data from the topography system T. It can employ a variety of algorithms, generally depending on the type of excimer laser system E. If the excimer laser system E employs a relatively large fixed spot size, for example, algorithms described in PCT Application Serial No. PCT/EP95/04028 can be used to develop a course of treatment based on an initial refractive profile and a desired refractive profile. Of course, a variety of laser systems and algorithms provide for treatment of irregular refractive errors, and software suitable for a particular laser system should be employed to develop the refractive profiles as illustrated in Figures 4A and 4B.

As will be appreciated, the technique can employ a variety of systems, such as an excimer laser system, a thermal system, radial keratotomy, or related systems, and employ a variety of diagnostic tools, such as a surface topography analysis system, a wavefront analysis system and the like.

The foregoing disclosure and description of the preferred embodiment are illustrative and explanatory thereof, and various changes in the components, circuit elements, circuit configurations, and signal connections, as well as in the details of the illustrated circuitry and construction and method of operation may be made without departing from the spirit and scope of the invention.

CLAIMS:

1. A method for refractive correction of a patient's eye, comprising:
making an asymmetric refractive correction resulting in a substantially symmetric residual refractive error profile; and
making a symmetric refractive correction of the substantially symmetric residual refractive error profile.
2. The method of claim 1, wherein the correcting steps provide for a remaining optical aberration in the patient's eye, such that a visual outcome is at least subjectively better than in the absence of any residual optical aberration.
3. The method of claim 1, further comprising:
determining an overall refractive error profile of the patient's eye prior to making the asymmetric correction; and
determining the symmetric residual refractive error profile prior to making the symmetric error correction.
4. The method of claim 1, wherein at least one of the steps of correcting includes the step of performing PRK.
5. The method of claim 1, wherein at least one of the steps of correcting includes the step of performing LASIK.
6. The method of claim 3, wherein at least one of the steps of determining further comprises the step of determining surface topography of the eye.
7. The method of claim 6, wherein the surface topography is determined using an elevation-based topography system.

8. The method of claim 3, wherein at least one of the steps of determining further comprises determining the error profile using surface elevation data and ray tracing.

9. The method of claim 3, wherein at least one of the steps of determining further comprises the step of determining wavefront aberrations of the eye.

10. The method of claim 1, wherein the first corrections step comprises the step of correcting for both high and low order errors of the eye.

11. The method of claim 1, wherein the second correcting step substantially corrects for defocus and astigmatism.

12. The method of claim 11, wherein the defocus and astigmatism are corrected employing empirical data.

13. The method of claim 1, wherein the patient's eye has previously undergone a refractive correction.

14. The method of claim 1, wherein the symmetric correction is made at some finite time after the asymmetric correction is made.

15. The method of claim 1, wherein the symmetric correction is made in real time following the asymmetric correction.

16. The method of claim 3, wherein the symmetric determining step is performed in real time following the asymmetric correction step.

17. The method of claim 3, wherein the symmetric determining step is performed at some finite time after the asymmetric correction step.

18. The method of claim 3, wherein the asymmetric determining step is performed by a topography technique and the symmetric determining step is performed by at least one of a wavefront sensing technique and a topographic technique.

19. A method of calculating a course of refractive treatment, comprising the steps of:

receiving refractive error profile data, indicative of a refractive error of the eye;

calculating a course of refractive treatment comprising a first stage of a multi-stage treatment that corrects a portion of the refractive error so as to yield a residual refractive error profile indicative of a refractive error wherein a course of refractive treatment for the residual error profile corresponds to a known course of treatment comprising a second stage of the multi-stage treatment; and

storing the calculated course of treatment.

20. A system for calculating a course of refractive treatment, comprising:
a computer system that receives refractive diagnostic eye data; and
means for calculating and storing a first treatment profile suitable to substantially remove decentration and other asymmetries present in the refractive eye data.

21. A system for calculating a course of refractive treatment, comprising:
a computer system that receives refractive diagnostic eye data indicative of a refractive error of the eye; and

computer software that when executed by the computer system, calculates a first treatment profile, which is, based upon the refractive diagnostic eye data, the first treatment profile suitable to correct a portion of the refractive error such that a residual refractive error substantially corresponds to a known course of treatment.

22. The system of claim 21, where the known course of treatment is for myopia, hyperopia, or astigmatism.

23. The system of claim 21, wherein the portion of the error comprises decentration and other asymmetric refractive errors.

24. A multi-stage course of treatment for a refractive correction of a patient's eye, comprising:

a first-stage treatment including a first treatment course suitable for correcting an asymmetric refractive error profile of the eye; and

a second-stage treatment including a second treatment course suitable for correcting a residual refractive error profile of the eye.

25. The course of treatment of claim 24, wherein the asymmetric refractive error profile includes decentration and other asymmetric refractive errors.

26. The course of treatment of claim 24, wherein the residual refractive error profile corresponds to at least one of myopia, hyperopia and astigmatism.

27. The course of treatment of claim 24, wherein the residual refractive error profile has an empirical correspondence to a known course of treatment.

28. The course of treatment of claim 24, wherein the first-stage treatment includes a refractive diagnostic measurement of the eye.

29. The course of treatment of claim 28, wherein the refractive diagnostic measurement is one of a topographically related measurement and a wavefront measurement.

30. The course of treatment of claim 24, wherein the second-stage treatment includes a refractive diagnostic measurement of the eye.

31. The course of treatment of claim 30, wherein the refractive diagnostic measurement is one of a topographically related measurement and a wavefront measurement.

32. The course of treatment of claim 24, wherein the first stage treatment includes a topographically related diagnostic measurement and the second-stage treatment includes a wavefront related diagnostic measurement.

33. A method for determining a multi-stage refractive correction for a patient's eye, comprising:
obtaining an overall refractive treatment profile of the eye;
determining a largest symmetric profile of eye tissue removal consistent with the overall refractive treatment profile;
subtracting-out the largest symmetric profile from the overall profile so as to yield a treatment profile suitable to correct an asymmetric refractive error; and
obtaining another refractive treatment profile suitable to correct a residual refractive error.

34. The method of claim 33, wherein the overall refractive treatment profile and the another refractive treatment profile are each obtained with one of a topographically related diagnostic measurement and a wavefront related diagnostic measurement.

35. The method of claim 33, wherein the residual refractive error includes one of myopia, hyperopia and astigmatism.

36. The method of claim 33, wherein the residual refractive error corresponds to a known refractive treatment.

37. A method for a multi-stage refractive correction of a patient's eye, comprising:

determining said correction according to claim 33 and further comprising:
correcting the asymmetric refractive error after the subtracting-out step as
a first stage of the multi-stage correction; and
correcting the residual refractive error after obtaining the another
refractive error profile as a second-stage of the multi-stage refractive correction.

38. A method of claim 37 wherein the correcting steps comprise treating the eye with a laser beam.

39. A method for determining a multi-step refractive correction for a patient's eye, comprising:

obtaining an overall refractive treatment profile of the eye;
determining a symmetric profile of eye tissue removal that is less than a maximum symmetric profile of removal consistent with the overall refractive treatment profile;
subtracting-out the symmetric profile from the overall profile so as to yield a treatment profile suitable to correct an asymmetric refractive error; and
obtaining another refractive treatment profile suitable to correct a residual refractive error.

40. The method of claim 39, wherein the overall refractive treatment profile and the another refractive treatment profile are each obtained with one of a topographically related diagnostic measurement and a wavefront related diagnostic measurement.

41. The method of claim 39, wherein the residual refractive error includes one of myopia, hyperopia and astigmatism.

42. The method of claim 39, wherein the residual refractive error corresponds to a known refractive treatment.

43. A method for a multi-stage refractive correction of a patient's eye, comprising:
determining said correction according to claim 39 and further comprising:
correcting the asymmetric refractive error after the subtracting out step as a first stage of the multi-stage correction; and
correcting the residual refractive error after obtaining the another refractive error profile as a second-stage of the multi-stage refractive correction.

44. A method of claim 43 wherein the correcting steps comprise treating the eye with a laser beam.

45. A method for a multi-stage refractive treatment of a patient's eye, comprising:
performing a first-stage treatment including treating a gross asymmetric refractive error of the eye so as to yield a residual, generally symmetric refractive error;
and
performing a second-stage treatment including treating the residual, generally symmetric error.

46. The method of claim 45, wherein the residual, symmetric error can suitably be treated by a predictable treatment.

47. The method of claim 45, further comprising obtaining a topographically related refractive diagnostic measurement of the eye prior to the first-stage treatment;
and
obtaining a wavefront related refractive diagnostic measurement prior to the second-stage treatment.

48. A system for calculating a refractive treatment for a patient's eye, the system comprising software that, when executed, calculates a first treatment profile based upon refractive eye data, the first treatment profile suitable to substantially remove

decentration and other asymmetries present in the refractive eye data without completely correcting for the refractive eye data.

49. The system of claim 48, wherein the first treatment profile substantially corrects for all errors except myopia, hyperopia, and astigmatism.

50. A system for correcting for refractive errors in an eye in more than one step, comprising:

- a refractive diagnostic tool providing refractive eye data, including data indicating decentration and other asymmetries of refractive error;

- a refractive surgical correction system for correcting refractive error, including decentrations and other asymmetries; and

- a computing system that receives the refractive eye data from the refractive diagnostic tool and provides control data to the refractive surgical correction system, the computing system including software that, when executed, calculates a first treatment profile based upon refractive eye data, the first treatment profile suitable to substantially remove decentration and other asymmetries present in the refractive eye data without completely correcting for the refractive eye data.

51. The system of claim 50, wherein the first treatment profile substantially corrects for all errors except myopia, hyperopia, and astigmatism.

52. The system of claim 50, wherein the profile is calculated for a predetermined excimer laser eye surgery system.

53. The system of claim 50, wherein the refractive diagnostic tool is a wavefront sensor.

54. The system of claim 50, wherein the refractive diagnostic tool is a topography system.

55. The system of claim 54, wherein the topography system is a surface elevation based topography system employing ray tracing.

56. A multistage treatment for a refractive correction of a patient's eye, comprising:
making a first-stage treatment;
observing a first-stage biodynamical effect subsequent to the first-stage treatment;
observing a second-stage biodynamical response;
comparing the first-stage response to the second-stage response, and proceeding based upon said second-stage response.

57. The treatment of claim 56, wherein the second-stage response is empirically smaller than the first-stage response so as to provide a converging course of treatment.

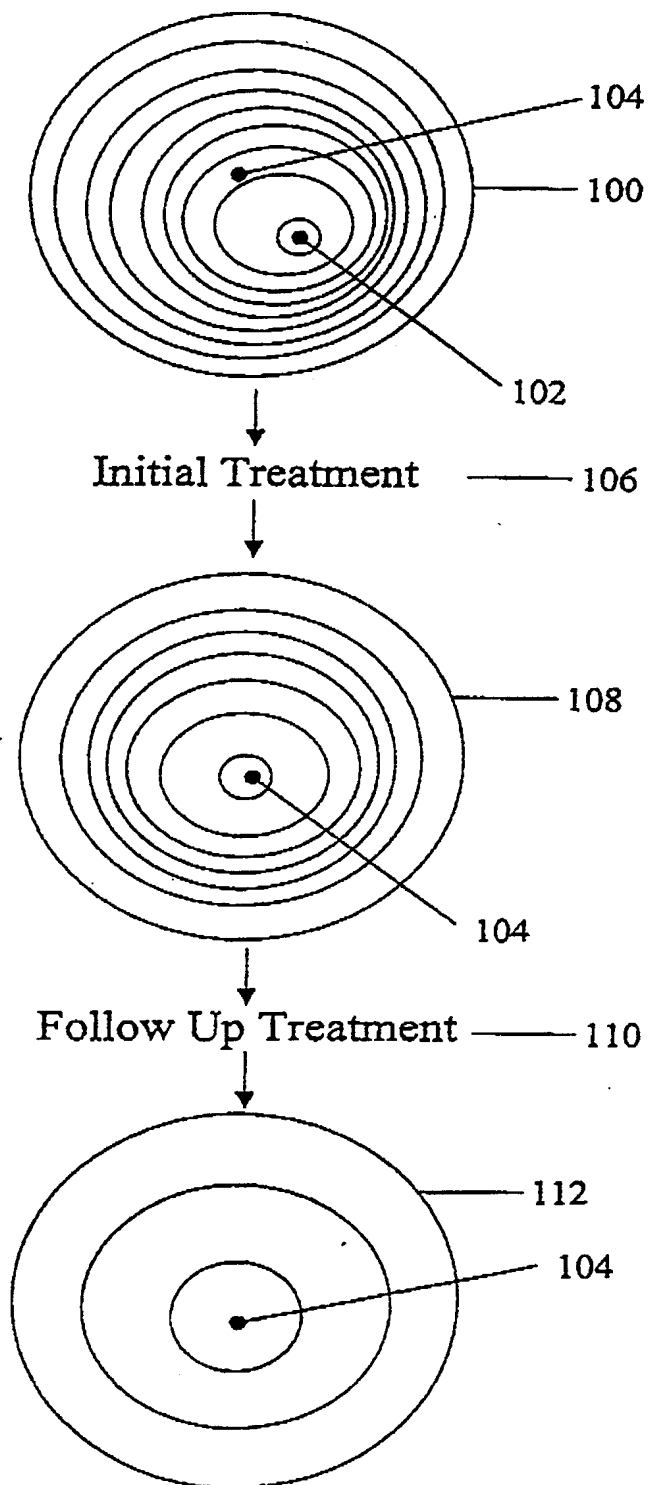


Fig. 1

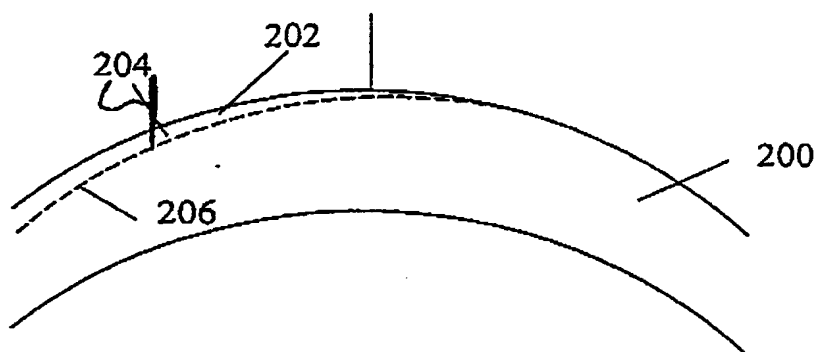


Fig. 2A

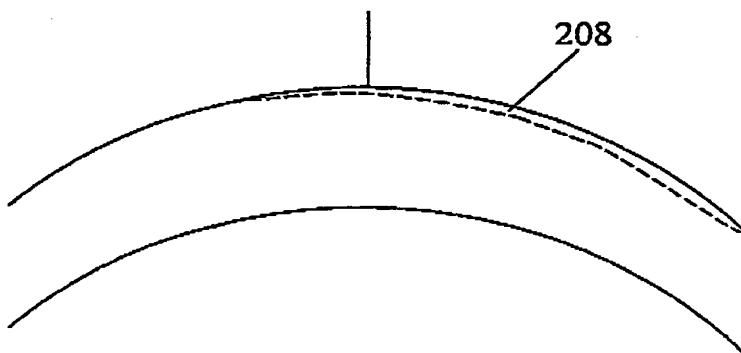


Fig. 2B

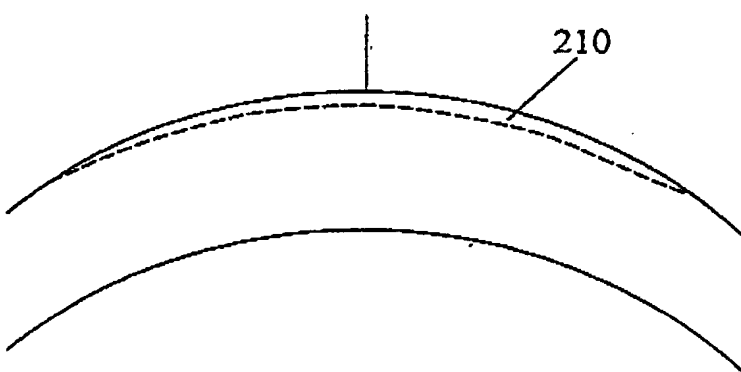


Fig. 2C

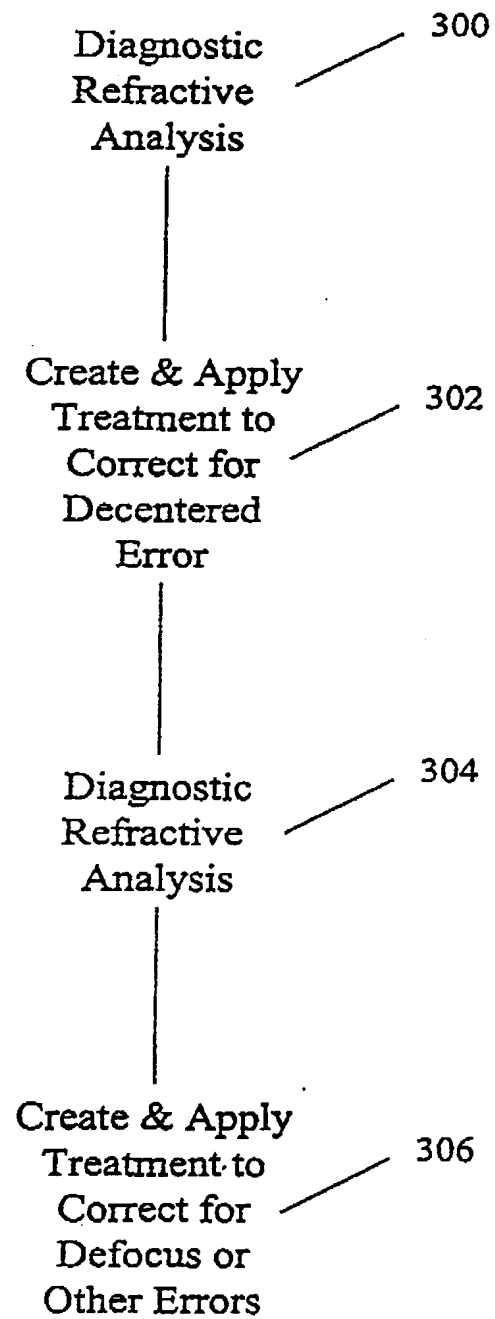


Fig. 3

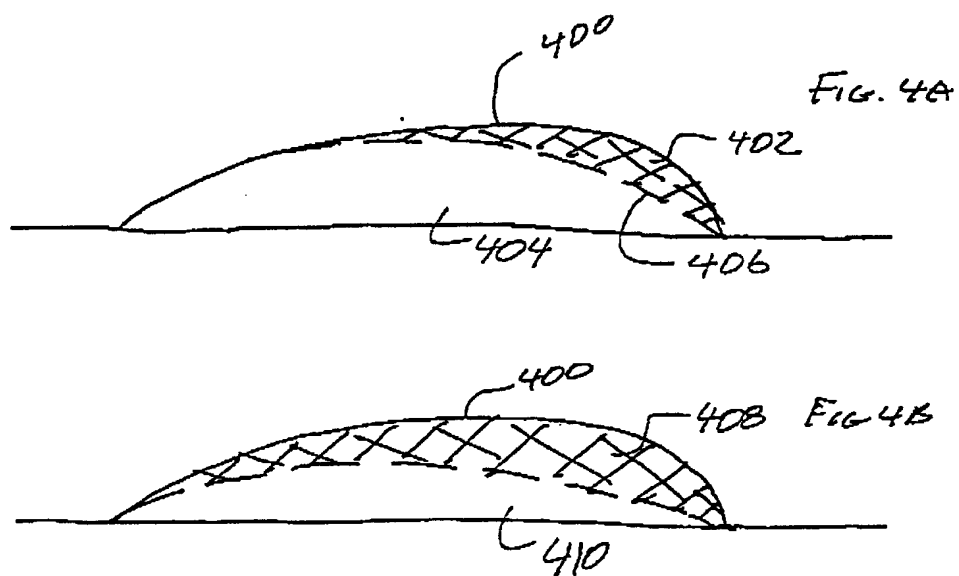


Fig. 4

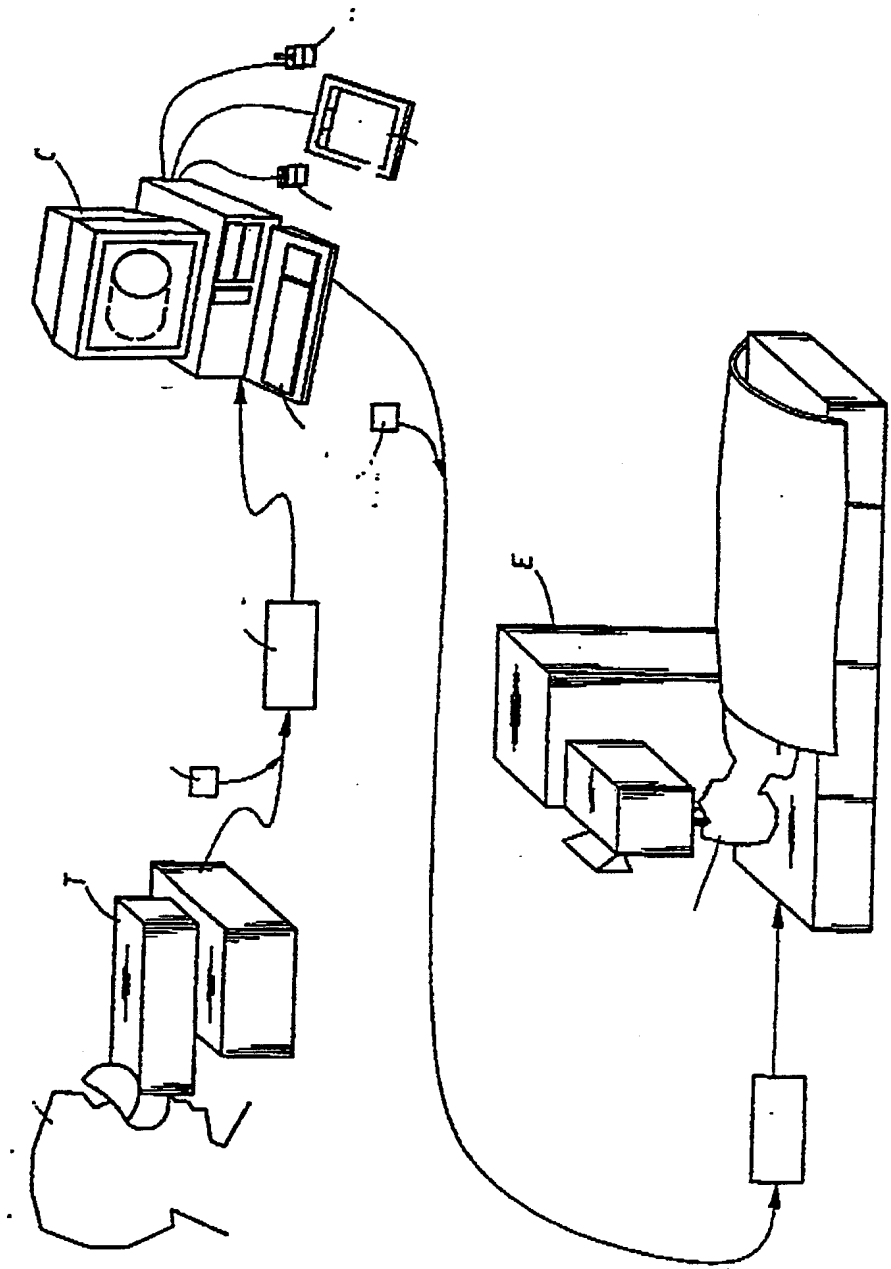


Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/10377

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61F9/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 11655 A (CHIRON TECHNOLOGAS) 25 April 1996 (1996-04-25) page 36, paragraph 2; figures 8,9,15,16 ---	20-22, 48-55
X	DE 197 27 573 C (AESCULAP) 20 May 1998 (1998-05-20) column 6 ---	21,22
X	WO 95 27535 A (SUMMIT) 19 October 1995 (1995-10-19) page 21 ---	21,22
X	WO 98 48746 A (CHIRON TECHNOLOGAS) 5 November 1998 (1998-11-05) page 9, paragraph 2 - paragraph 3 --- -/-	20



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

15 February 2001

Date of mailing of the international search report

26/02/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/10377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 132 A (HOHLA) 6 April 1999 (1999-04-06) figures 5,6 ---	20
A	US 5 423 801 A (MARSHALL) 13 June 1995 (1995-06-13) column 15; figures 1,8 ---	20-22, 48-55
A	US 5 777 719 A (WILLIAMS) 7 July 1998 (1998-07-07) cited in the application the whole document -----	53

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/10377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9611655 A	25-04-1996	US 6090100 A AU 713834 B AU 3805495 A CA 2202550 A EP 0785761 A JP 10509342 T	18-07-2000 09-12-1999 06-05-1996 25-04-1996 30-07-1997 14-09-1998
DE 19727573 C	20-05-1998	AU 5120598 A WO 9818415 A EP 0951260 A	22-05-1998 07-05-1998 27-10-1999
WO 9527535 A	19-10-1995	AU 2205395 A US 6056739 A	30-10-1995 02-05-2000
WO 9848746 A	05-11-1998	AU 7528898 A BR 9808977 A CN 1253487 T EP 1011563 A	24-11-1998 01-08-2000 17-05-2000 28-06-2000
US 5891132 A	06-04-1999	AU 715722 B AU 2962097 A BR 9709471 A CA 2251559 A CN 1230881 A WO 9746183 A EP 0902670 A JP 2000514321 T US 6139542 A	10-02-2000 05-01-1998 11-01-2000 11-12-1997 06-10-1999 11-12-1997 24-03-1999 31-10-2000 31-10-2000
US 5423801 A	13-06-1995	US 4856513 A AT 69717 T AU 7160687 A DE 3774815 A DE 3774815 D EP 0261193 A WO 8705496 A JP 1500086 T JP 4033220 B US 4994058 A US 5324281 A US 5019074 A	15-08-1989 15-12-1991 09-10-1987 09-01-1992 09-01-1992 30-03-1988 24-09-1987 19-01-1989 02-06-1992 19-02-1991 28-06-1994 28-05-1991
US 5777719 A	07-07-1998	AU 723645 B AU 5806298 A BR 9714178 A CN 1245406 A EP 0969760 A US 5949521 A WO 9827863 A	31-08-2000 17-07-1998 29-02-2000 23-02-2000 12-01-2000 07-09-1999 02-07-1998